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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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LIBERTY MUTUAL INSURANCE COMPANY, LIBERTY MUTUAL FIRE INSURANCE COMPANY, LIBERTY INSURANCE CORPORATION, THE FIRST LIBERTY INSURANCE CORPORATION, LM INSURANCE CORPORATION, LIBERTY MUTUAL MID-ATLANTIC INSURANCE COMPANY, LIBERTY COUNTY MUTUAL INSURANCE COMPANY, LM PROPERTY and CASUALTY INSURANCE COMPANY, SAFECO COMPANY OF INDIANA, and AMERICAN STATES INSURANCE COMPANY,

Plaintiffs,

-against-

WOODSIDE CHEMISTS, INC., RONIKA SONI, LAM C. QUAN, M.D., LEONID REYFMAN, M.D., LEONID LITOVSKIY, P.A., ROBERT B. LANTER, D.O., MAXIM TYORKIN, M.D., PERICLES S. HADJIYANE, M.D., TIMOTHY CANTY, M.D., JAMES A. GRIFFIN, P.A.

Defendants.

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Docket No.:_____ ( )

Plaintiffs Demand a Trial by Jury

COMPLAINT

Plaintiffs Liberty Mutual Insurance Company, Liberty Mutual Fire Insurance Company, Liberty Insurance Corporation, The First Liberty Insurance Corporation, LM Insurance Corporation, Liberty Mutual Mid-Atlantic Insurance Company, Liberty County Mutual Insurance Company, LM Property and Casualty Insurance Company, Safeco Company of Indiana, and American States Insurance Company (collectively, "Liberty Mutual" or "Plaintiffs"), as and for its Complaint against Defendants, hereby allege as follows:

NATURE OF THE ACTION

1. This action seeks to recover approximately $20,500.00 that the Defendants wrongfully have stolen from Liberty Mutual, and extinguish approximately $222,400.00 in pending fraudulent billing, resulting from the submission of fraudulent claims seeking payment for medically unnecessary, illusory, and formulaic compounded "pain relieving" drug products ("Fraudulent Compounded Pain Creams") allegedly provided to individuals involved in automobile accidents and eligible for insurance coverage under policies of insurance issued by Liberty Mutual ("Insureds").

2. Woodside Chemists, Inc. ("Woodside Chemists") and its alleged owner, Ronika Soni ("Soni"), purport to be a neighborhood pharmacy, but Woodside Chemists illegally engaged in bulk "compounding," exclusively dispensing large quantities of the Fraudulent Compounded Pain Creams in set formulations, without tailoring the medications to the individual needs of any patient. The Fraudulent Compounded Pain Creams are not approved by the United States Food and Drug Administration ("FDA"), but Woodside Chemists, in an egregious scheme to exploit the Insureds' "No-Fault" insurance benefits, intentionally assembled a combination of drug ingredients with unproven topical therapeutic effects for the sole purpose of creating exorbitantly priced topical compounded pain cream products – for which it billed New York State automobile insurers approximately $2,000.00 to in excess of $6,000.00 for a single tube. The Defendants

engaged in this scheme all while knowing that there were a wide range of commercially available, FDA-approved medications with proven therapeutic effects available at a fraction of the cost that could have been dispensed to the patients.

3. To implement the fraudulent scheme, Woodside Chemists and Soni entered into illegal, collusive arrangements involving the payment of unlawful kickbacks to licensed physicians and/or their associates working at various multidisciplinary medical "clinics" that treat patients with no-fault insurance benefits (the "No-Fault Clinics"), in order to generate formulaic, coded, and unnecessary prescriptions for the Fraudulent Compounded Pain Creams. The Fraudulent Compounded Pain Creams were produced by Woodside Chemists in large quantities, were not medically necessary, and were dispensed solely to financially enrich the Defendants, rather than to treat or otherwise benefit the Insureds who purportedly received them.

4. In addition to recovering damages resulting from this fraudulent scheme, Liberty Mutual seeks a declaration that it is not legally obligated to pay Woodside Chemists approximately $222,400.00 in pending fraudulent claims the Defendants submitted or caused to be submitted through Woodside Chemists because:

(i) The Defendants produced and dispensed the Fraudulent Compounded Pain Creams pursuant to predetermined fraudulent protocols solely to financially enrich themselves, based on prescriptions solicited by Woodside Chemists without regard for the topical efficacy of the compounded pain creams or the availability of a wide range of commercially available, FDA-approved medications proven to have therapeutic effects available at a fraction of the cost;

(ii) the Defendants participated in illegal, collusive agreements in which Woodside Chemists solicited and received formulaic, medically unnecessary prescriptions from licensed physicians and/or their associates for the Fraudulent Compounded Pain Creams produced by Woodside in exchange for unlawful kickbacks paid by Woodside Chemists and its alleged owner, Soni; and

(iii) Woodside Chemists engaged in illegal bulk compounding by producing and exclusively dispensing large quantities of the Fraudulent Compounded

Pain Creams in set formulations, in violation of Federal and New York State regulatory and licensing requirements imposed on pharmacies, drug manufacturers and outsourcing facilities, rendering it ineligible to receive reimbursement for No-Fault insurance benefits.

5. The Defendants fall into the following categories:

(i) Woodside Chemists is a New York corporation engaged in a fraudulent scheme in which it produces and solely dispenses the Fraudulent Compounded Creams to patients and then submits bills to Liberty Mutual and other New York automobile insurers for reimbursement to which it is not entitled;

(ii) Soni is the purported owner of Woodside Chemists (Soni and Woodside Chemists are collectively referred to as the "Pharmacy Defendants").

(iii) Lam C. Quan, M.D. ("Quan"), Leonid Reyfman, M.D. ("Reyfman"), Leonid Litovskiy, P.A. ("Litovskiy"), Robert B. Lanter, D.O. ("Lanter"), Maxim Tyorkin, M.D. ("Tyorkin"), Pericles S. Hadjiyane, M.D. ("Hadjiyane"), Timothy Canty, M.D. ("Canty"), and James A. Griffin, P.A. ("Griffin") (collectively, the "Prescribing Defendants") are physicians, physician assistants, and their associates who, in exchange for kickbacks, prescribed, or purported to prescribe, the medically unnecessary Fraudulent Compounded Pain Creams that are produced and dispensed by Woodside Chemists.

6. The Defendants' scheme began in 2015 and continues uninterrupted to the present day. As discussed more fully below, the Defendants at all times have known that: (i) the Defendants produced and dispensed the Fraudulent Compounded Pain Creams pursuant to predetermined fraudulent protocols designed solely to financially enrich themselves, based on prescriptions solicited by Woodside Chemists, without regard for the topical efficacy of the compounded pain creams or the availability of a wide range of commercially available, FDA-approved medications proven to have therapeutic effects, which are available at a fraction of the cost; (ii) the Defendants participated in illegal, collusive agreements in which Woodside Chemists solicited and received formulaic, medically unnecessary prescriptions from licensed physicians and/or their associates for the Fraudulent Compounded Pain Creams produced by Woodside in exchange for unlawful kickbacks paid by Woodside Chemists and its alleged

owner, Soni; and (iii) Woodside Chemists engaged in illegal bulk compounding by producing and exclusively dispensing large quantities of the Fraudulent Compounded Pain Creams in set formulations, in violation of Federal and New York State regulatory and licensing requirements imposed on pharmacies, drug manufacturers and outsourcing facilities, rendering it ineligible to receive reimbursement for No-Fault benefits;

7. As such, Woodside Chemists does not now have – and never had – any right to be compensated for the Fraudulent Compounded Pain Creams allegedly dispensed to Liberty Mutual insureds. The chart attached hereto as Exhibit "1" sets forth the fraudulent claims that have been identified to-date which the Defendants submitted, or caused to be submitted, to Liberty Mutual. As a result of the Defendants' scheme, Liberty Mutual has incurred damages of approximately $20,500.00

THE PARTIES

I. Plaintiffs

8. Plaintiffs Liberty Mutual Insurance Company and Liberty Mutual Mid-Atlantic Insurance Company are Massachusetts corporations with their principal place of business in Boston, Massachusetts. Liberty Mutual Insurance Company and Liberty Mutual Mid-Atlantic Insurance Company are authorized to conduct business and to issue policies of automobile insurance in the State of New York.

9. Plaintiffs Liberty Insurance Corporation, The First Liberty Insurance Corporation and LM Insurance Corporation are Illinois corporations with their principal place of business in Boston, Massachusetts. Liberty Insurance Corporation, The First Liberty Insurance Corporation and LM Insurance Corporation are authorized to conduct business and to issue policies of automobile insurance in the State of New York.

10. Plaintiff Liberty Mutual Fire Insurance Company is a Wisconsin corporation with its principal place of business in Boston, Massachusetts. Liberty Mutual Fire Insurance Company is authorized to conduct business and to issue policies of automobile insurance in the State of New York.

11. Plaintiff Liberty County Mutual Insurance Company is a Texas corporation with its principal place of business in Boston, Massachusetts. Liberty County Mutual Insurance Company is authorized to conduct business and to issue policies of automobile insurance in the State of New York.

12. Plaintiffs LM Property and Casualty Insurance Company, Safeco Company of Indiana, and American States Insurance Company are Indiana corporations with its principal place of business in Boston, Massachusetts. LM Property and Casualty Insurance Company, Safeco Company of Indiana, and American States Insurance Company are authorized to conduct business and to issue policies of automobile insurance in the State of New York.

II. Defendants

13. Defendant Woodside Chemists is a New York corporation with its principal place of business at 58-01 Woodside Avenue, Woodside, New York, through which the Fraudulent Compounded Pain Creams have been billed to insurance companies, including Liberty Mutual.

14. Woodside Chemists was incorporated on December 23, 2015, and from December 2015 through the present day, knowingly has submitted fraudulent claims to Liberty Mutual and continues to seek reimbursement on unpaid fraudulent claims.

15. Woodside Chemists engages in pharmaceutical compounding activities and exclusively dispenses compounded pain creams.

16. Woodside Chemists is registered with New York State as a pharmacy, but is not registered as a manufacturer or outsourcing facility and, thus, is not permitted to engage in bulk compounding or exclusively dispense compounded pain creams.

17. Defendant Soni resides in and is citizen of New York. Soni is the owner of, listed officer of, and registered agent for Woodside Chemists.

18. Quam resides in and is a citizen of New York. Quam was licensed to practice medicine in New York on August 8, 2006. Quam knowingly has participated in a scheme to prescribe the Fraudulent Compounded Creams to Liberty Mutual Insureds.

19. Reyfman resides in and is a citizen of New York. Reyfman was licensed to practice medicine in New York on June 29, 2004. Reyfman knowingly has participated in a scheme to prescribe the Fraudulent Compounded Creams to Liberty Mutual Insureds.

20. Litovskiy resides in and is a citizen of New York. Litovskiy was licensed as a physician assistant in New York on March 26, 2012. Litovskiy worked for Reyfman as a physician assistant, and knowingly has participated in a scheme to prescribe the Fraudulent Compounded Creams to Liberty Mutual Insureds.

21. Lanter resides in and is a citizen of New York. Lanter was licensed to practice medicine in New York on February 23, 1990. Lanter knowingly has participated in a scheme to prescribe the Fraudulent Compounded Creams to Liberty Mutual Insureds.

22. Tyorkin resides in and is a citizen of New York. Tyorkin was licensed to practice medicine in New York on March 15, 2006. Tyorkin knowingly has participated in a scheme to prescribe the Fraudulent Compounded Creams to Liberty Mutual Insureds.

23. Hadjiyane resides in and is a citizen of New York. Hadjiyane was licensed to practice medicine in New York on January 26, 1995. Hadjiyane knowingly has participated in a scheme to prescribe the Fraudulent Compounded Creams to Liberty Mutual Insureds.

24. Canty resides in and is a citizen of New York. Canty was licensed to practice medicine in New York on August 30, 2005. Canty knowingly has participated in a scheme to prescribe the Fraudulent Compounded Creams to Liberty Mutual Insureds.

25. Griffin resides in and is a citizen of New York. Griffin was licensed as a physician assistant in New York on August 24, 1979. Griffin worked for Canty as a physician assistant, and knowingly has participated in a scheme to prescribe the Fraudulent Compounded Creams to Liberty Mutual Insureds.

JURISDICTION AND VENUE

26. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §1332(a)(1) because the matter in controversy exceeds the sum or value of $75,000.00, exclusive of interest and costs, and is between citizens of different states.

27. Venue in this District is appropriate pursuant to 28 U.S.C. § 1391, as the Eastern District of New York is the District where one or more of the Defendants reside and because this is the District where a substantial amount of the activities forming the basis of the Complaint occurred.

ALLEGATIONS COMMON TO ALL CLAIMS

I. An Overview of New York's No-Fault Laws

28. Liberty Mutual underwrites automobile insurance in the State of New York.

29. New York's "No-Fault" laws are designed to ensure that injured victims of motor vehicle accidents have an efficient mechanism to pay for and receive the healthcare services that they need. Under New York's Comprehensive Motor Vehicle Insurance Reparations Act (N.Y. Ins. Law §§ 5101 et seq.) and the regulations promulgated pursuant thereto (11 N.Y.C.R.R. §§ 65 et seq.)(collectively, referred to herein as the "No-Fault Laws"), automobile insurers are required to provide Personal Injury Protection Benefits ("No-Fault Benefits") to Insureds.

30. No-Fault Benefits include up to $50,000.00 per Insured for necessary expenses that are incurred for health care goods and services.

31. An Insured can assign his or her right to No-Fault Benefits to the providers of healthcare services in exchange for those services. Pursuant to a duly executed assignment, a healthcare provider may submit claims directly to an insurance company and receive payment for necessary goods and medical services provided, using the claim form required by the New York State Department of Insurance (known as the "Verification of Treatment by Attending Physician or Other Provider of Health Service," or, more commonly, as an "NF-3"). In the alternative, healthcare providers sometimes submit claims using the Health Care Financing Administration insurance claim form (known as the "HCFA-1500 Form").

32. Pursuant to New York's No-Fault Laws (11 N.Y.C.R.R. § 65-3.16(a)(12)), a healthcare provider is not eligible to receive No-Fault Benefits if it fails to meet any applicable New York state or local licensing requirement necessary to perform such services in New York.

33. In State Farm Mut. Auto. Ins. Co. v. Mallela, 4 N.Y.3d 313 (2005), the New York Court of Appeals, relying on the implementing regulation, 11 N.Y.C.R.R. § 65-3.16(a)(12), made clear that healthcare providers that fail to comply with licensing requirements are ineligible to collect No-Fault benefits. The Court of Appeals further provided that insurers may look beyond a facially-valid license to determine whether there was a failure to abide by state and local law.

34. Pursuant to New York Insurance Law § 403, the NF-3s and HCFA-1500 Forms submitted by a healthcare provider to Liberty Mutual, and to all other automobile insurers, must be verified by the health care provider subject to the following warning:

> Any person who knowingly and with intent to defraud any insurance company or other person files an application for insurance or statement of claim containing any materially false information, or conceals for the purpose of misleading,

information concerning any fact material thereto, commits a fraudulent insurance act, which is a crime.

II. An Overview of Applicable Licensing Laws

35. The United States Federal Food, Drug, and Cosmetic Act ("FDCA") authorizes the United States Food and Drug Administration ("FDA") to oversee the safety of food, drugs, and cosmetics.

36. Pursuant to New York Education Law § 6808, no person, firm, corporation or association shall possess drugs, prescriptions or poisons for the purpose of compounding, dispensing, retailing, wholesaling or manufacturing, or shall offer drugs, prescriptions or poisons for sale at retail or wholesale unless registered by the New York State Department of Education as a pharmacy, wholesaler, manufacturer or outsourcing facility.

37. Manufacturers and outsourcing facilities that seek to register with the New York State Department of Education, as required by New York State Education Law § 6808, must also register with the FDA and be listed as a manufacturer or outsourcing facility on the FDA website.

38. Education Law § 6530(38) prohibits a licensed physician from entering into an arrangement or agreement with a pharmacy for the compounding and/or dispensing of coded or specially marked prescriptions, while Education Law § 6811 makes it a crime for any person to enter into an agreement with a physician (or other licensed healthcare provider) for the compounding or dispensing of secret formula ("coded") prescriptions.

39. Education Law § 6530(18) prohibits a licensed physician from "directly or indirectly" offering, giving, soliciting, receiving or agreeing to receive any fee or other consideration to or from a third party in exchange for patient referrals or in connection with the performance of professional services.

40. Education Law § 6509-a, prohibits a professional licensee from "directly or indirectly" requesting, receiving, or participating in the division, transference, assignment, rebate, splitting, or refunding of a fee in connection with professional care or services including services related to drugs and/or medications.

41. 8 N.Y.C.R.R. § 29.1(b)(3) prohibits a professional licensee from "directly or indirectly" offering, giving, soliciting, or receiving or agreeing to receive, any fee or other consideration to or from a third party for the referral of a patient or client or in connection with the performance of professional services.

III. An Overview of Compounded Drug Products

42. The FDA strictly regulates over-the-counter and prescription drugs, and oversees drug manufacturing in several ways, including testing drugs and routinely inspecting drug manufacturing plants and outsourcing facilities engaged in the compounding of drugs.

43. FDA-approved drugs require approval prior to marketing, compliance with federal labelling laws, and they must be made and tested in accordance with good manufacturing practice regulations (GMPs), which are federal statutes that govern the production and testing of pharmaceutical products.

44. Pursuant to Section 503A of the Federal Food, Drug and Cosmetic Act ("FDCA"), as amended by the Compounding Quality Act, the laws applicable to drugs regulated by the FDA, including the laws relating to the safe manufacturing of drugs, generally do not apply to a "compounded" drug product: (1) if the drug product is compounded for an identified individual patient based on the receipt of a valid prescription order that a compounded product is necessary for the identified patient, and (2) if the compounding is by a licensed pharmacist in a state licensed pharmacy.

45. The FDA defines traditional pharmacy compounding as the combining, mixing, or altering of ingredients to create a customized medication for an individual patient in response to a licensed practitioner's prescription. Traditional pharmacy compounding plays a role in providing access to medications for patients with unique medical needs, which cannot otherwise be met with a commercially available product. State licensed pharmacies may compound specified medications when an FDA-approved drug product is not available or appropriate for a patient, including strength or route of delivery.

46. Compounded drugs are generally not FDA-approved, though they may include FDA-approved drugs, and are generally exempt from the FDA approval process which applies to new drugs if the drug is compounded for an identified individual patient based on the receipt of a valid prescription, approved by the prescribing practitioner on the prescription order, that a compounded product is necessary for the identified patient. See, 21 U.S.C. § 353a.

47. Unlike FDA-approved products, consumers and prescribers cannot assume that compounded drugs were made by validated processes in properly calibrated and cleaned equipment; that the ingredients in the drug were obtained from FDA-approved sources; that production personnel had the requisite knowledge and training; and that appropriate laboratory testing was performed to verify the compounded drug's potency, purity, and quality.

48. The FDA has publically expressed concern regarding large-scale drug manufacturing under the guise of traditional small-scale pharmacy compounding. For example, the FDA has noted that poor practices on the part of bulk drug compounders can result in contamination or products that do not possess the strength, quality, and purity required. Published reports also consistently show that compounded drugs fail to meet specifications at a considerably higher rate than FDA-approved drugs.

49. Traditional pharmacy compounding by state licensed pharmacies, therefore, is permissible when done on a small scale by pharmacists who prepare the medication based on an individual prescription. Specifically, when compounded drugs meet the requirements of 21 U.S.C. § 353a and are compounded for an individual patient, they can be exempted from the requirement, among others, that they be FDA-approved. See, 21 U.S.C. § 355(a) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to... this section is effective with respect to such drug").

50. When Congress adopted 21 U.S.C. § 353a, its express intent was to "ensure continued availability of compounded drug products as a component of individualized therapy, while limiting the scope of compounding so as to prevent manufacturing [of drugs that would otherwise require FDA approval] under the guise of compounding." H.R. Rep. No. 105-399, at 94 (1997) (Conf. Rep.)(emphasis added). As Congress stated at the time:

> the "exemptions in [this section] are limited to compounding for an individual patient based on the medical need of such patient for the particular drug compound. To qualify for the exemptions, the pharmacist or physician must be able to cite to a legitimate medical need for the compounded product that would explain why a commercially available drug product would not be appropriate. Although recording the medical need directly on each prescription order would not be required, this technique would be one of many acceptable ways of documenting the medical need for each compounded drug product. This medical need would not include compounding drugs that are essentially copies of commercially available drug products for largely economic reasons. The pharmacist may rely on appropriately documented input from the physician as to whether a commercially available drug product is not appropriate for the identified individual patient."

S. Rep. No. 105-43, at 67-68 (1997)(emphasis added).

51. Because compounded products are not FDA-approved, and therefore, not subject to FDA regulations regarding quality, safety and effectiveness of manufactured drug products, they should never be prescribed as a matter of routine therapy, and should only be prescribed to

meet a legitimate specific need of an individual patient, or when all other forms of oral and/or topical medications approved for the treatment of pain have failed.

52. Prior to receiving a prescription for any compounded drug product, a patient's medical records should document all other forms of FDA-approved drugs that were prescribed and failed to treat the symptom for which the compounded drug product was then prescribed, and/or the medical rationale that supports the otherwise premature prescription of a compounded drug product.

53. Recently, the prescription of compounded drug products and ensuing billing to both private and public insurers has been the subject of state and federal investigations and litigation due to increased concerns regarding fraud.

54. For example, in January 2014, the United States Attorney for the District of New Jersey filed a criminal complaint against a defendant pharmacist, who thereafter pled guilty, in connection with a fraudulent scheme involving payment of kickbacks to a physician in exchange for prescriptions for compounded pain creams. See USA v. Kleyman, 1:14-CR-598-JHR, Docket No. 1. In February 2016, the United States Attorney for the Northern District of Texas arrested and indicted two layperson defendants, who conspired with physicians and pharmacies, in a scheme involving producing, prescribing, and distributing compound creams, including payment of kickbacks to prescribing physicians and insured beneficiaries. See USA v. Cesario, 3:16-CR-060-M, Docket Nos. 3, 75. In June 2016, the United States Attorney for the Middle District of Florida indicted a physician who engaged in a fraudulent scheme with numerous co-conspirators involving payment of kickbacks for the referral of patients and prescriptions for compounded creams. See USA v. Baldizzi, 8:16CR271-MSS-AEP, Docket No. 1.

55. In August 2016, the United States Attorney for the Southern District of New York arrested and indicted more than 40 members of the Genovese, Gambino, Luchese, and Bonanno

crime families, whose alleged illegal activities included "causing...corrupt doctors to issue unnecessary and excessive prescriptions for expensive compound cream" billed to insurers. See, USA v. Parrello, 16 Crim. 522 (2016). See also U.S. Department of Health & Human Services, Office of Inspector General, High Part D Spending on Opioids and Substantial Growth in Compound Drugs Raise Concerns, HHS OIG Data Brief, OEI-16-00290 (June 2016); Office of Inspector General, United States Postal Services, Worker's Compensation Compound Drug Costs, Management Advisory, Report No. HR-MA-16-003 (March 14, 2016). The USPS OIG attributed fraud as one of the causes for the "unprecedented increases" in compound drug costs and referenced the "alarming discovery" of physicians prescribing compounded drugs to patients whom they never examined, and fraud schemes involving physicians prescribing medically unnecessary compound drugs in exchange for kickbacks. Id.

IV. The Defendants' Fraudulent Scheme Involving The Fraudulent Compounded Creams

56. Beginning in 2015, and continuing uninterrupted through the present day, the Defendants masterminded and implemented a fraudulent scheme in which the Defendants have used Woodside Chemists to bill the New York automobile insurance industry for reimbursement – which it is not eligible to receive – of the Fraudulent Compounded Pain Creams purportedly provided to Insureds.

57. Despite purporting to be a neighborhood pharmacy, Woodside Chemists produced and exclusively dispensed large quantities of the Fraudulent Compounded Pain Creams, which were not approved by the FDA, in set formulations, without tailoring the medications to the individual needs of any individual patient, and without complying with licensing requirements that are designed to ensure the quality, safety and effectiveness of bulk compounded drug products.

58. Woodside Chemists, rather than dispensing commercially available, FDA-approved medications with proven efficacy, intentionally produced and dispensed exorbitantly priced compounded "pain creams" (i.e., the Fraudulent Compounded Pain Creams") by intentionally assembling combinations of expensive drug ingredients without regard to the absence of any proven topical efficacy of the combination of ingredients, for which it billed New York automobile insurers approximately $2,000.00 to in excess of $6,000.00 for a single tube of cream.

59. The Defendants knew that the topical efficacy of the Fraudulent Compounded Pain Creams that Woodside Chemists produced and dispensed was unproven and knew that there was a wide range of commercially available, FDA-approved medications proven to have therapeutic effects available at a fraction of the cost.

60. The Defendants, solely to maximize profits, had Woodside Chemists engage in illegal compounding, producing large quantities of compounded drugs in set formulations, as part of collusive arrangements made with licensed physicians and their associates (the "Prescribing Defendants ") to compound and dispense specially marked, formulaic prescriptions.

61. Woodside Chemists, unlike a legitimate licensed state licensed pharmacy, exclusively engaged in the production and dispensation of the Fraudulent Compounded Pain Creams.

62. The Defendants, intentionally utilizing the large quantity of formulaic Fraudulent Compounded Pain Creams produced by Woodside Chemists, arranged to have the Prescribing Defendants issue "stamped" predetermined prescriptions, so that the Fraudulent Compounded Pain Creams could be dispensed and billed pursuant to the Defendants' pre-determined, fraudulent protocol.

63. Specifically, pursuant to the Defendants' fraudulent scheme, and in exchange for unlawful kickbacks, the Prescribing Defendants, operating from No-Fault Clinics that treat thousands of Insureds, purported to prescribe the medically unnecessary and illusory Fraudulent Compounded Pain Creams to the Insureds, which in turn permitted the Defendants to bill Liberty Mutual for the Fraudulent Compounded Pain Creams under the name of Woodside Chemists.

64. To conceal the scheme, the Pharmacy Defendants presented Woodside Chemists as a legitimate, neighborhood pharmacy engaged in lawful, limited pharmacy drug compounding in response to valid prescriptions received from the Prescribing Defendants.

65. Notwithstanding the Defendants' attempt to conceal the scheme and present Woodside Chemists as a neighborhood pharmacy, the Defendants directly violated New York State and Federal regulatory and licensing requirements that govern large-scale drug compounders, drug manufacturers and outsourcing facilities and which prohibit collusive arrangements for compounding and/or dispensing of coded or specially marked prescriptions – all of which poses a huge threat to the health and safety of the patients and general public.

66. The Fraudulent Compounded Pain Creams produced by Woodside Chemists (i) were not medically necessary; (ii) contained a combination of ingredients that produced no significant difference between the compounded drug and comparable commercially available products; (iii) were almost never prescribed properly under the governing regulations; and (iv) were "prescribed" and produced in large quantities without regard to medical necessity or the regulations governing the appropriate use of compounded drug products, as part of unlawful kickback arrangements.

67. In short, the Fraudulent Compounded Pain Creams produced by Woodside Chemists, and prescribed by the physicians and their associates working in collusion with

Woodside Chemists, served no purpose other than to exploit the Insureds' No-Fault benefits so as to financially benefit the Defendants.

A. Woodside Chemists Engaged in Large Scale Drug Compounding Activity in Violation of New York State and Federal Law Governing Drug Manufacturers and Outsourcing Facilities

68. As stated above, compounded drug products are only appropriate in limited circumstances, should be formulated for an individual patient's needs upon receipt of a valid prescription for an identified individual or a notation on a prescription stating that a compounded product is necessary for the identified patient, and should not be prescribed and dispensed as a matter of course.

69. The Defendants, however, blatantly exploited the No-Fault insurance reimbursement system by entering into collusive relationships involving the manufacturing, marketing, and soliciting of prescriptions for the same set of predetermined Fraudulent Compounded Pain Creams that were dispensed again and again to numerous Insureds involved in minor fender-bender type accidents, generating hundreds of thousands of dollars in fraudulent billing to insurers.

70. Woodside Chemists, at all relevant times, engaged exclusively in creating and dispensing the Fraudulent Compounded Pain Creams.

71. Woodside Chemists did not, and does not, dispense any drug products or medications except for the Fraudulent Compounded Pain Creams.

72. Woodside Chemists, acting under the guise of a neighborhood pharmacy, intentionally assembled a combination of expensive drug ingredients solely to produce exorbitantly priced topical compounded pain creams that it could market to the Prescribing Defendants in return for the payments of kickbacks.

73. In furtherance of the scheme, the Pharmacy Defendants gave the Prescribing Defendants a set list of the Fraudulent Compounded Pain Creams that Woodside Chemists created, via a series of "prescription stamps" that contained the name of the compounded pain cream and the formulation, including the names of the particular drug ingredients and percentage concentrations of each ingredient used.

74. For example, the Pharmacy Defendants produced, marketed and dispensed, among others, the following predetermined, formulaic Fraudulent Compounded Pain Creams:

- BCCFGL pain cream, with the following ingredients:
    - Baclofen
    - Capsaicin
    - Cyclobenzaprine Hydrochloride
    - Flurbiprofen
    - Gabapentin
    - Lidocaine
- BCFGLM pain cream, with the following ingredients:
    - Baclofen
    - Cyclobenzaprine Hydrochloride
    - Flurbiprofen
    - Gabapentin
    - Lidocaine
    - Menthol
- DMCLT pain cream, with the following ingredients:
    - Diclofenac Sodium
    - Menthol
    - Cyclobenzaprine Hydrochloride
    - Lidocaine
    - Tetracaine Hydrochloride
- KGBCF pain cream, with the following ingredients:
    - Ketamine
    - Gabapentin
    - Baclofen
    - Cyclobenzaprine Hydrochloride
    - Flurbiprofen

75. Woodside Chemists typically billed New York automobile insurers (i) $6,008.00 for single tube of the BCCFGL pain cream; (ii) $4,306.82 for a single tube of BCFGLM pain cream; (iii) $1,989.11 for a single tube of the DMCLT pain cream, and (iv) $3,971.76 for a single tube of the KGBCF pain cream.

76. The Fraudulent Compounded Pain Creams were not created or prescribed by the Prescribing Defendants to meet the unique needs of any individual patient.

77. Instead, the Fraudulent Compounded Pain Creams were produced and dispensed by Woodside Chemists in large quantities without regard to the unique needs of any individual patient.

78. As part of the collusive arrangement with the Prescribing Defendants, the Pharmacy Defendants produced and distributed the predetermined and Fraudulent Compound Pain Creams, together with a series of "prescription stamps," bearing the names, ingredients, and concentrations of those predetermined and formulaic compounded products, which stamps the Prescribing Defendants then used to stamp their official New York State prescription pads to prescribe the Fraudulent Compounded Creams to the Insureds.

79. Through the use of the specially marked, or coded prescriptions, with the "prescription stamps," the Pharmacy Defendants steered the Prescribing Defendants to prescribe the Fraudulent Compounded Pain Creams as part of a predetermined treatment, billing and kickback scheme.

80. Despite the fact that traditional pharmacy compounding requires the combining, mixing, or altering of ingredients to create a customized medication for an individual patient in response to a licensed practitioner's prescription, the prescriptions containing the "prescription

stamps" indicate that the Pharmacy Defendants produced the Fraudulent Compounded Pain Creams in bulk.

81. Accordingly, the Fraudulent Compounded Pain Creams, prescribed by the Prescribing Defendants, and manufactured by the Pharmacy Defendants, were not customized for individual patients. The Fraudulent Compounded Pain Creams varied only in that there were a limited number of, predetermined Fraudulent Compounded Pain Creams from which to choose.

82. A representative sample of the standard "prescription stamps" used to prescribe the Fraudulent Compounded Pain Creams to Insureds, and which the Defendants submitted to Liberty Mutual in support of their fraudulent billing, are annexed hereto as Exhibit "2".

83. In addition to the "prescription stamps," the Pharmacy Defendants gave the Prescribing Defendants pre-printed "Letter of Medical Necessity" forms, bearing Woodside Chemists' name, address, and contact information, for the Prescribing Defendants to submit to insurers to attempt to justify the compounded drug products as medically necessary.

84. The "Letter of Medical Necessity" forms allegedly supporting the prescription of the Fraudulent Compounded Pain Creams were created by the Pharmacy Defendants.

85. The "Letter of Medical Necessity" forms allegedly supporting the prescription of the Fraudulent Compounded Pain Creams were not created by the Prescribing Defendants.

86. The "Letter of Medical Necessity" forms were actually pre-printed, boilerplate, and required only that the prescribing physician write the name of the patient, the diagnosis, circle pre-printed treatments provided to the patient, and select one or more predetermined reasons for prescribing the Fraudulent Compounded Pain Creams.

87. A representative sample of the standard "Letter of Medical Necessity" forms used to attempt to justify the medical necessity of the prescriptions for the Fraudulent Compounded

Pain Creams to Insureds, and which the Defendants submitted to Liberty Mutual in support of their fraudulent billing, are annexed hereto as Exhibit "3".

88. The Pharmacy Defendants, not the Prescribing Defendants, created the boilerplate reasons purportedly supporting the prescription of the Fraudulent Compounded Pain Creams, which included the following:

(i) The patient has failed to improve, still has significant symptoms and findings, in spite of the use of commercial products

(ii) The patient is intolerant of commercial [sic] available products

(iii) Attempt to avoid gastrointestinal problems secondary to oral ingestion

(iv) Substantial avoidance, or reduction of systemic exposure, avoidance of sedation, and avoidance of high serum levels of drug

(v) Reduce risk of side effects and drug interactions compared to oral ingestion

(vi) Patient has documented difficulties ingesting oral medication

(vii) The compounded medication prescribed will work well in conjunction with current therapies (ex: PT, Chiropractic Therapy)

(viii) To avoid or reduce the risk of addiction to oral narcotics medication.

89. Through the use of the pre-printed, boilerplate Letter of Medical Necessity forms, the Pharmacy Defendants steered the Prescribing Defendants to attest to the purported medical necessity of the Fraudulent Compounded Pain Creams in order to conceal the fact that the prescription and dispensation of the compounded drug products was part of a predetermined treatment, billing and kickback scheme.

90. Even so, a substantial number of the "Letter of Medical Necessity" forms submitted to Liberty Mutual were incomplete or essentially blank, in that the Prescribing Defendants often failed to list a diagnosis, circle any printed treatments provided to the patient,

and/or select one of the predetermined reasons for prescribing the Fraudulent Compounded Pain Creams.

91. What is more, even if the "Letter of Medical Necessity" forms were completed, many of the pre-printed reasons for prescribing the Fraudulent Compounded Pain Creams would not justify the prescription of the Fraudulent Compounded Pain Creams as medically necessary, even if the compounded drug products had any proved efficacy and even if the reasons for dispensing them were indicated on the "Letter of Medical Necessity" forms.

92. For example, the mere fact that "[t]he compounded medication prescribed will work well in conjunction with current therapies (ex: PT, Chiropractic Therapy)" – even if true – would not make the Fraudulent Compounded Pain Creams medically necessary. Although a traditional pharmacy compounded product may be appropriate when an FDA-approved drug product is not available or appropriate for a patient, including strength or route of delivery, such as in a case where a patient has unique medical needs that cannot otherwise be met with a commercially available product, compounded drug products are not appropriate merely because they would complement chiropractic or physical therapy services.

93. What is more, and in further keeping with the fact that the Fraudulent Compounded Pain Creams were predetermined and produced in large volumes, the "Letter of Medical Necessity" forms were not specific to any of the individual predetermined products.

94. The "Letter of Medical Necessity" forms – which were generally incomplete – were designed to be nothing more than a "one size fits all" template to create the appearance of justification for the dispensation of the predetermined Fraudulent Compounded Pain Creams in large volumes, notwithstanding that the compounded drug products were required to be customized to meet the unique needs of an individual patient.

95. In approximately one year, Woodside Chemists submitted billing to Liberty alone with charges totaling more than $300,000.00, all of which related to the Fraudulent Compounded Pain Creams allegedly issued to Liberty's Insureds.

96. Given that Liberty's Insureds make up only a fraction of the New York insurance market, it is axiomatic that the Pharmacy Defendants produce hundreds of thousands of dollars more of the Fraudulent Compounded Pain Products during the course of approximately one year, which they billed to other New York insurance companies.

97. Woodside Chemists, by exclusively creating and dispensing large volumes of the Fraudulent Compounded Pain Creams, engaged in bulk compounding activity (akin to that engaged in by drug manufacturers and outsourcing facilities) as opposed to compounding individual prescriptions on a case-by-case basis upon receipt of a valid prescription order.

98. The Pharmacy Defendants' creation and dispensation of predetermined, compounded drug products in large volumes, together with supplying pre-printed, boilerplate "Letter of Medical Necessity" forms to the Prescribing Defendants, renders Woodside Chemists in violation of both state and federal licensing laws regulating the safe manufacturing of drugs.

99. Woodside Chemists and the Fraudulent Compounded Pain Creams are not exempt from FDA oversight and approval, and similar New York state licensing requirements applicable to drug manufacturers and outsourcing facilities, because the Fraudulent Compounded Pain Creams were clearly not individualized and tailored to meet specific individual patient needs; were not provided pursuant to legitimate prescriptions; and were illegally compounded in set formulations in large quantities. See, 21 U.S.C. § 355 and 21 U.S.C. 353a(a).

100. Furthermore, as drug manufacturers and dispensers, the Pharmacy Defendants violated 21 U.S.C. § 355(a) which states that "no person shall introduce or deliver for

introduction into interstate commerce any new drug" without first obtaining approval to do so by way of an application filed with the Secretary with respect to that drug.

101. A "new drug" – as defined by 21 U.S.C. § 321(p)(1) – is "any drug…the composition of which is such that such drug is not generally recognized…as safe and effective for use under the conditions prescribed, recommended or suggested in the labeling thereof."

102. Woodside Chemists' Fraudulent Compounded Pain Creams – for which it has billed Liberty Mutual hundreds of thousands of dollars – have never been FDA-approved and, therefore, were never verified by the FDA as being safe, effective or quality products. In fact, Woodside Chemists' bulk compounding and dispensing of the Fraudulent Compounded Pain Creams exposed Insureds to widespread risks including harmful contraindications, which is why they should have only been prescribed under unique circumstances in limited circumstances.

B. The Prescription and Dispensation of Woodside Chemists' Compounded Creams Was Contrary to Evidenced-Based Medical Practices

103. In keeping with the fact that the Fraudulent Compounded Creams were prescribed pursuant to the Defendants' fraudulent scheme intended to generate profits from insurers, Woodside Chemists' Fraudulent Compounded Pain Creams (i) had no medical efficacy based on the purported symptoms of the patients receiving the compounded products; (ii) were prescribed and administered repeatedly as first line therapy contrary to evidenced-based medical practices; and (iii) were prescribed without any legitimate reason to provide the patients with expensive compounded products – which include drugs whose efficacy in topical form is undocumented and unsupported – when there are many other widely accepted, proven effective alternatives with well documented therapeutic benefits commercially available at considerably lower costs.

104. Evidence-based guidelines for the treatment of acute pain do exist and should always guide prescribing habits. The World Health Organization ("WHO") pain relief ladder

recommends a non-opioid such as acetaminophen or a nonsteroidal anti-inflammatory drug (NSAID) for the initial management of pain. NSAIDs are the most commonly prescribed analgesic medications worldwide, and their efficacy for treating acute pain has been well demonstrated. If pain relief is not achieved, then an adjuvant oral agent may be added to the medication regimen – including the use of muscle relaxers, and medications that block neuropathic pain transmission. Finally, opiates may be prescribed for short-term, limited use. Clinical studies of FDA-approved topical NSAIDs have shown them to be no more effective than placebo for treating acute pain (e.g., from strains, sprains, contusions, or overuse injuries) in superficial locations.

105. Because compounded products, like the ones dispended by Woodside Chemists, are not FDA-approved – and therefore not subject to FDA regulations regarding quality, safety and effectiveness of manufactured drug products – they should never be prescribed as routine therapy; should only be prescribed to meet a legitimate specific need of an individual patient, or when all other forms of oral and/or topical medications approved for the treatment of pain have failed, or there is a contraindication for use.

106. Topical compounded creams should be the last prescribed intervention after oral medications are not tolerated or are deemed ineffective as well as any FDA-approved manufactured topical products have also been shown to provide no pain relief to the patient.

107. For a topical formulation to be effective, it must first penetrate the skin. In general, creams are less effective than gels or sprays.

108. The skin is composed of three layers: epidermis, dermis, and hypodermis. Within the epidermis, the stratus corneum is the outermost layer of the skin that serves as the main barrier to drug entry. For analgesic medicines to be absorbed through the skin, they must contain optimal drug combinations, effective concentrations of each drug, and a compounding base with

the appropriate physiochemical properties to facilitate absorption.

109. In order for a drug to alleviate pain, it must reach nerve or tissue receptors responsible for producing or transmitting a person's sensation of pain.

110. Oral pain relievers reduce or alleviate pain by entering the bloodstream through the gastrointestinal system and traveling to the relevant nerve or tissue receptors. Some of the limited circumstances in which a physician would prescribe a topical medication include patients in whom these oral medications are contraindicated – those with moderate to severe kidney or liver dysfunction, or those with comorbidities that preclude the use of oral nonsteroidal anti-inflammatory drugs (e.g., history of peptic ulcer disease or congestive heart failure).

111. Woodside Chemists' Fraudulent Compounded Pain Creams contain combinations of drugs that make no clinical sense and have no efficacious value in treating musculoskeletal and neuropathic injuries – even assuming that the Insureds the Prescribing Defendants treated actually suffered from such injuries.

112. There are no published, peer-reviewed, controlled studies to support that patients who suffer from musculoskeletal pain or neuropathy have achieved any therapeutic effect from using topical pain creams containing the drugs that are part of the Fraudulent Compounded Pain Creams.

113. Further, many of the Fraudulent Compounded Pain Creams are available in oral formulations or are commercially available in different topical formulations. These alternatives are proven to therapeutically benefit patients with musculoskeletal and neuropathic pain, are FDA-approved, and are commonly recommended and prescribed among healthcare providers who utilize evidence-based medicine for their prescribing practices.

114. Contrary to evidenced-based medical practices, the Fraudulent Compounded Pain Creams were routinely prescribed by the Prescribing Defendants and administered as first line therapy.

115. The Prescribing Defendants failed to practice evidence-based medicine; rather, the Prescribing Defendants prescribed the Fraudulent Compounded Pain Creams pursuant to a fraudulent predetermined treatment, billing and kickback protocol designed to enrich all of the Defendants.

116. Indeed, the Prescribing Defendants prescribed the Fraudulent Compounded Pain Creams during their initial examinations and before the patient had any opportunity to improve and/or complete any course of more conservative treatments.

117. The Prescribing Defendants also failed to recommend that the Insureds first try over-the-counter FDA-approved topical medications and assess their effectiveness, prior to prescribing the Fraudulent Compounded Pain Creams produced and dispensed by the Pharmacy Defendants in large quantities.

118. Further, the Prescribing Defendants did not document in their examination reports that the patients were intolerant of commercially available products.

119. The Prescribing Defendants did not document in their examination reports why any compounded drug product was medically necessary, or why the particular Fraudulent Compounded Pain Product they ultimately prescribed for the patient was medically necessary.

120. The "Letter of Medical Necessity" forms submitted with the bills to Liberty also were not specific to any of the individual predetermined, formulaic Fraudulent Compounded Pain Creams.

121. The Prescribing Defendants also failed to document in their follow up examination reports whether the Fraudulent Compounded Pain Product prescribed to a particular patient was actually used by the patient.

122. The Prescribing Defendants also failed to document in their follow up examination reports whether the Fraudulent Compounded Pain Product provided any pain relief to the patient or was otherwise effective for the purpose prescribed.

123. The Prescribing Defendants plainly failed to prescribe individually tailored compounded products, made for an identified individual Insured, which produced a significant difference between the compounded drug and a comparable commercially available product.

124. Likewise, Woodside Chemists never dispensed individually tailored compounded products, made for an identified individual Insured, which produced a significant difference between the compounded drug and a comparable commercially available product. In fact, Woodside Chemists never dispensed any other prescriptions medications, aside from the Fraudulent Compounded Pain Creams, despite purporting to be a neighborhood pharmacy.

125. The combination of drugs used in the Fraudulent Compounded Pain Creams was merely a means for the Defendants to inflate the billing and maximize their charges to exploit New York automobile insurance carriers, as pharmacy providers are ordinarily statutorily reimbursed for each individual ingredient contained in a compounded drug product. As a result, the more drug ingredients that Woodside Chemists included in its Fraudulent Compounded Pain Creams, the more that the Pharmacy Defendants could bill under the name of Woodside Chemists.

126. Finally, in keeping with the fact that the Fraudulent Compounded Creams were prescribed for the financial benefit of the Defendants, rather than for the benefit of the Insureds, the Prescribing Defendants routinely include multiple refills of the Fraudulent Compounded Pain

Creams in their initial prescriptions – often doubling or tripling the total amounts ultimately billed to Liberty Mutual – without regard for whether the Fraudulent Compounded Pain Creams actually provided any therapeutic relief to the Insureds.

C. The Fraudulent Compounded Pain Creams Were Prescribed and Dispensed Without Regard to Genuine Patient Care

127. In basic terms, the goal of medical treatment is to help patients get better in a timely manner. Notwithstanding this basic goal, the Insureds treated by the Prescribing Defendants were virtually always subjected to a predetermined treatment protocol, which was both unnecessarily prolonged and totally lacking in individualized care, which did not utilize evidence based practices with the goal of the Insureds timely return to good health. Conversely, the treatment reports almost uniformly reflected that the Insureds treated by the Prescribing Defendants did not get better, did not return to good health, and/or did not experience improvement in their conditions such that the Insureds could terminate medical treatment expeditiously and return to normal activity.

128. As part of the predetermined protocol, the Prescribing Defendants produced examination reports that were generic, preprinted, and boilerplate, designed to justify continuing, voluminous and excessive healthcare services that the No-Fault Clinic providers purported to render to Insureds thereafter – including the prescription of Fraudulent Compounded Pain Creams.

129. Notwithstanding the creation of the examination reports, the Prescribing Defendants' prescriptions of the Fraudulent Compounded Pain Creams were not medically necessary and were based on a pre-determined protocol, provided without regard to the genuine needs of the patients.

130. To the extent any examination was actually performed at all, the Prescribing Defendants failed to document a detailed medical history of the patients to whom they prescribed the Fraudulent Compounded Pain Creams. Prescribing compounded products without first taking a detailed patient history demonstrates a gross indifference to patient health and safety as the Prescribing Defendants did not know whether the patient was currently taking any medication or suffering from any co-morbidities that would contraindicate the use of a compounded drug product.

131. The Prescribing Defendants' failure to document a detailed medical history of the patients to whom they prescribed the Fraudulent Compounded Pain Creams is also indicative that the Prescribing Defendants did not prescribe the compounded drug products to meet the unique needs of a particular patient that could not be met with an existing FDA-approved medication because the inadequate examinations would not be able to identify any such unique needs.

132. What is more, many of the Prescribing Defendants' initial examination reports and follow-up examination reports made no mention whatsoever of the specific Fraudulent Compounded Pain Creams the Insureds were prescribed.

133. The Prescribing Defendants' inadequate initial examination and follow-up examination reports provide further evidence that (i) the Fraudulent Compounded Pain Creams were not medically necessary and were provided and billed for pursuant to a pre-determined fraudulent protocol; (ii) the Fraudulent Compounded Pain Creams were not individually tailored to meet the unique needs of a particular patient in response to a valid prescription and, therefore, not FDA-exempt; (iii) the Pharmacy Defendants and the Prescribing Defendants were engaged in collusive kickback arrangements; and (iv) Woodside Chemists is not a neighborhood

pharmacy, but a large scale manufacturer and producer of predetermined, mass produced drug products acting in violation of law.

D. The Illegal, Collusive Kickback Arrangements Between Woodside Chemists and the Prescribing Defendants

134. In furtherance of the fraudulent scheme, the Defendants participated in illegal, collusive arrangements in which the Prescribing Defendants named herein, (along with the other prescribing providers, prescribed the medically unnecessary Fraudulent Compounded Pain Creams in exchange for unlawful kickbacks paid by the Pharmacy Defendants.

135. The Pharmacy Defendants arranged with various No-Fault Clinics that treat thousands of Insureds to have the licensed physicians and/or their associates operating therefrom, prescribe, or purport to prescribe, the medically unnecessary and illusory Fraudulent Compounded Pain Creams to the Insureds, which in turn permitted the Pharmacy Defendants to bill Liberty Mutual huge sums under the name of Woodside Chemists.

136. In exchange for kickbacks paid by the Pharmacy Defendants to the Prescribing Defendants, the Prescribing Defendants prescribed, or purported to prescribe, the Fraudulent Compounded Pain Creams to patients of the No-Fault Clinics pursuant to the Defendants' fraudulent predetermined treatment, billing and kickback protocol, without regard to genuine patient care, without regard to pharmacologic outcomes, and without regard to cost and attention to fiscal responsibility.

137. In exchange for kickbacks paid by the Pharmacy Defendants to the Prescribing Defendants, the Prescribing Defendants prescribed, or purported to prescribe, the Fraudulent Compounded Pain Creams to patients of the No-Fault Clinics pursuant to formulaic, coded "prescriptions," stamped with the name and formula of one of the Fraudulent Compounded Pain Creams produced by Woodside Chemists.

138. The "stamped" prescriptions were nothing more than a "cover" for the predetermined issuance of formulaic and unnecessary compounded pharmaceuticals designed to exploit the patients' No-Fault insurance benefits.

139. In fact, the Prescribing Defendants prescribed, or purport to prescribe, the Fraudulent Compounded Pain Creams to patients of the No-Fault Clinics, despite their knowledge that the Fraudulent Compounded Pain Creams were not customized or tailored to the individual needs of a particular patient; despite their knowledge that there were FDA-approved drugs available and appropriate for the particular patients; and despite their knowledge that the Fraudulent Compounded Pain Creams were prescribed in large volumes without regard to genuine patient care, without regard to pharmacologic outcomes, and without regard to cost and attention to fiscal responsibility.

140. In keeping with the fact that the Fraudulent Compounded Pain Creams were prescribed for the financial benefit of the Prescribing Defendants and the Pharmacy Defendants, rather than for the benefit of the Insureds, the Insureds virtually never received the prescriptions themselves to fill (even though the prescriptions were paper prescriptions) and were not given the option to use a pharmacy of their choosing.

141. The Insureds often were given the Fraudulent Compounded Pain Creams directly from the front desk staff at the various No-Fault Clinics without ever seeing the actual prescription. Alternatively, Woodside Chemists purported to mail or deliver the Fraudulent Compounded Pain Creams directly to the Insureds' homes, again without the patient ever receiving the actual written prescription.

142. The Insureds often were not even aware they were to receive any medications until they were given the Fraudulent Compounded Pain Creams by the front desk staff or received a package containing the pain cream.

143. The Prescribing Defendants did not give the Insureds the option to identify a pharmacy of their choosing to ensure that the prescriptions were filled by Woodside Chemists and to ensure that the Pharmacy Defendants benefitted financially from the prescriptions.

144. But for the payments of kickbacks from the Pharmacy Defendants, the Prescribing Defendants had no legitimate reason to prescribe the predetermined, medically unnecessary Fraudulent Compounded Pain Creams, which were not individually tailored to meet a unique need of a particular patient, in large quantities.

E. The Fraudulent Billing the Defendants Submitted or Caused to be Submitted to Liberty Mutual

145. The maximum amount that a healthcare provider may charge for a medically necessary compounded product is based on each individual ingredient included in the compounded product. Each prescribed ingredient, whether a brand name or generic drug, included in a compounded product has a designated national drug code ("NDC") – a unique 10-digit code that identifies the drug itself, the vendor of the drug and the quantity in which the drug was packaged. Each NDC number has an assigned Average Wholesale Price ("AWP").

146. Each NDC (and, thus, the AWP) for a particular ingredient differs depending on both the particular supplier the drug is purchased from and the quantity in which the drug is obtained. The same drug can have a different NDC number if it is purchased from a different supplier and/or in different quantities.

147. Pursuant to 12 N.Y.C.R.R. §§ 440.5(a) and (d) (the "Pharmacy Fee schedule"), for each brand name drug included in a compounded product, a provider may charge no more than the AWP assigned to that particular NDC on the day the drug was dispensed minus 12% of the AWP, plus a single dispensing fee of $4.00.

148. For each generic drug included in a compounded product, the provider may charge no more than the AWP assigned to that particular NDC on the day the drug was dispensed minus 20% of the AWP, plus a single dispensing fee of $5.00.

149. AWP is defined by 12 N.Y.C.R.R. § 440.2(a) as:

> "[t]he average wholesale price of a prescription drug as provided in the most current release of the Red Book published by Thomson Reuters or Medi-Span Master Drug Database by Wolters Kluwar Health or any successor publisher, on the day a prescription drug is dispensed or other nationally recognized drug pricing index adopted by the Chair or Chair's designee."

150. When a pharmacist bills for dispensing compounded products, it must bill based on the actual NDC number (and the assigned AWP) of each of the ingredients dispensed as part of the compounded product. It cannot use the NDC of the same ingredient available from a different supplier and/or purchased in different quantities in order to inflate the assigned AWP.

151. The Pharmacy Defendants purported to provide the Fraudulent Compounded Pain Creams – billed through Woodside Chemists – directly to Liberty Mutual Insureds, and sought reimbursement directly from Liberty Mutual pursuant to executed "Assignment of Benefit" ("AOB") forms. With regard to compounded products, Woodside Chemists' bills list each ingredient separately along with the corresponding charge for each. The total billed amount for Woodside Chemists' compounded products varies from approximately $2,000.00 to in excess of $6,000.00 for a single Fraudulent Compounded Pain Product.

152. In support of its charges, Woodside Chemists submitted: (i) the Prescribing Defendants' prescription forms, bearing the pre-printed "prescription stamps"; (ii) the pre-printed – and often incomplete – "Letters of Medical Necessity"; (iii) a "No-Fault" form, known as an NF-3 Form, which includes the purported NDC numbers, units, and corresponding charges for each ingredient in the billed-for Fraudulent Compounded Product; (iv) an invoice from Woodside Chemists listing the quantities of the compounds in the Fraudulent Compounded Pain

Creams, the name of the prescribing physician, and the total amount due; and (v) the AOB in which the Insured assigned their benefits to Woodside Chemists.

153. The NDC numbers listed on the NF-3 Forms submitted by Woodside Chemists identify the various alleged sources from which Woodside Chemists obtains the ingredients for its Compounded Creams and the alleged AWPs for such products.

154. Notably, Woodside Chemists never submits its purchase invoices demonstrating how much Woodside Chemists paid the supplier for the ingredients or the quantities in which the ingredients were obtained.

155. The Pharmacy Defendants, purely to exploit the No-Fault reimbursement regulations relating to pharmaceutical products, intentionally assembled large combination of drugs to produce each of the Fraudulent Compounded Pain Creams.

156. The combination of numerous drugs in each of the Fraudulent Compounded Pain Creams have no proven, documented topical therapeutic effect different than commercially available, FDA products available at a fraction of the cost.

157. The sole reason for the Pharmacy Defendants' intentional assembling of large combinations of drugs was to inflate the charges and maximize their billing to exploit New York automobile insurance carriers, as pharmacy providers are ordinarily statutorily reimbursed for each individual ingredient contained in a compounded drug product.

VI. The Defendants' Submission of Fraudulent NF-3 Forms to Liberty Mutual

158. To support the fraudulent charges, statutorily prescribed claim forms for No-Fault Benefits consistently have been submitted to Liberty Mutual by and on behalf of Woodside Chemists seeking payment for the pharmaceuticals for which it is ineligible to received payment.

159. These forms, including NF-3 forms, HCFA-1500 forms and other supporting records that the Defendants submitted or caused to be submitted to Liberty Mutual, were false and misleading in the following material respects:

(i) The NF-3 forms, HCFA-1500 forms, and other supporting records uniformly misrepresented to Liberty Mutual that the Fraudulent Compounded Pain Creams were medically necessary. In fact, the Pharmacy Defendants produced and dispensed the Fraudulent Compounded Pain Creams pursuant to predetermined fraudulent protocols solely to financially enrich themselves, based on prescriptions solicited by Woodside Chemists without regard for the topical efficacy of the compounded drug creams or the availability of a wide range of commercially available, FDA-approved medications proven to have therapeutic effects available at a fraction of the cost.

(ii) The NF-3 forms, HCFA-1500 forms, and other supporting records uniformly misrepresented to Liberty Mutual that the Pharmacy Defendants complied with all material licensing laws and, therefore, are eligible to receive No-Fault Benefits pursuant to Insurance Law § 5102(a)(1) and 11 N.Y.C.R.R. § 65-3.16(a)(12). In fact, the Pharmacy Defendants did not comply with all material licensing laws in that the Defendants participated in illegal, collusive agreements in which Woodside Chemists solicited and received formulaic and unnecessary prescriptions from licensed physicians and/or their associates for the Fraudulent Compounded Pain Creams exclusively produced by Woodside Chemists in exchange for unlawful kickbacks paid by Woodside Chemists and its alleged owner, Soni; and

(iii) The NF-3 forms, HCFA-1500 forms, and other supporting records uniformly misrepresented to Liberty Mutual that the Pharmacy Defendants complied with all material licensing laws and, therefore, are eligible to receive No-Fault Benefits pursuant to Insurance Law § 5102(a)(1) and 11 N.Y.C.R.R. § 65-3.16(a)(12). In fact, the Pharmacy Defendants did not comply with all material licensing laws in that they engaged in illegal bulk compounding by exclusively producing and dispensing large quantities of the Fraudulent Compounded Pain Creams in set formulations, in violation of Federal and New York State regulatory and licensing requirements imposed on drug manufacturers and outsourcing facilities, rendering Woodside Chemists ineligible to receive reimbursement for No-Fault insurance benefits.

VII. The Defendants' Fraudulent Concealment and Liberty Mutual's Justifiable Reliance

160. The Defendants are legally and ethically obligated to act honestly and with integrity in connection with the provision of pharmaceutical products to Insureds and the billing

they submit or cause to be summited to Liberty Mutual seeking reimbursement for these products.

161. To induce Liberty Mutual to promptly pay the charges for the Fraudulent Compounded Creams, the Defendants have gone to great lengths to systematically conceal their fraud.

162. Specifically, the Defendants knowingly have misrepresented and concealed facts in an effort to prevent discovery that the Defendants (i) violated licensing laws governing manufacturers and large-scale drug outsourcing facilities of compounded drugs; (ii) have been involved in collusive, kickback arrangements to generate voluminous prescriptions pursuant to a fraudulent pre-determined treatment, billing, and kickback protocol, without regard to genuine patient care; and (iii) prescribed and dispensed Fraudulent Compounded Pain Creams that have no efficacious value and grossly exceed the cost of effective FDA-approved medications; and (v) intentionally assembled large combinations of drugs into purported compounded pain creams solely to inflate the billing to Liberty Mutual and other New York insurance companies.

163. In accordance with the No-Fault Laws, Liberty Mutual either: (i) timely denied the pending claims for No-Fault Benefits submitted through Woodside Chemists; (ii) timely issued requests for additional verification with respect to the pending claims for No-Fault Benefits submitted through Woodside Chemists, yet failed to obtain complete compliance with the requests for additional verification; or else (iii) the time in which to deny the pending claims for No-Fault Benefits submitted through Woodside Chemists, or to request additional verification of those claims, has not yet expired.

164. The Defendants have hired law firms to pursue collection of the fraudulent charges from Liberty Mutual and other insurers. These law firms routinely file expensive and time-consuming litigation against Liberty Mutual and other insurers if the charges are not

promptly paid in full. In fact, Woodside Chemists continues to have legal counsel pursue collection against Liberty Mutual and other insurers without regard for the fact that Woodside Chemists has been engaged in fraud.

165. Liberty Mutual is under statutory and contractual obligations to promptly and fairly process claims within 30 days. The facially-valid documents that were submitted to Liberty Mutual in support of the fraudulent charges at issue, combined with the material misrepresentations described above, were designed to and did cause Liberty Mutual to rely upon them. As a result, Liberty Mutual has incurred damages of approximately $20,500.00 representing payments made by Liberty Mutual based upon the fraudulent charges submitted by the Defendants.

166. Based upon the Defendants' material misrepresentations and other affirmative acts to conceal their fraud from Liberty Mutual, Liberty Mutual did not discover and could not reasonably have discovered that its damages were attributable to fraud until shortly before it filed this Complaint.

THE FIRST CLAIM FOR RELIEF
Against the Pharmacy Defendants
(Declaratory Judgment – 28 U.S.C. §§ 2201 and 2202)

167. Liberty Mutual incorporates, as though fully set forth herein, each and every allegation in the paragraphs set forth above.

168. There is an actual case in controversy between Liberty Mutual and the Defendants regarding approximately $222,400.00 in fraudulent billing for the Fraudulent Compounded Creams that has been submitted to Liberty Mutual.

169. Defendants have no right to receive payment for any pending bills submitted to Liberty Mutual because:

(i) the Defendants made false and fraudulent misrepresentations to Liberty Mutual in that the Fraudulent Compounded Pain Creams were not medically necessary and were provided – to the extent they were provided at all –pursuant to predetermined fraudulent protocols designed solely to financially enrich themselves, based on prescriptions solicited by Woodside Chemists without regard for the topical efficacy of the compounded drug creams or the availability of a wide range of commercially available, FDA-approved medications proven to have therapeutic effects available at a fraction of the cost;

(ii) the Defendants engaged in illegal, collusive agreements in which Woodside Chemists solicited and received formulaic and unnecessary prescriptions from licensed physicians and/or their associates for the Fraudulent Compounded Pain Creams produced by Woodside in exchange for unlawful kickbacks paid by Woodside Chemists and its alleged owner, Soni; and

(iii) Woodside Chemists engaged in illegal bulk compounding by exclusively producing and dispensing large quantities of the Fraudulent Compounded Pain Creams in set formulations, in violation of Federal and New York State regulatory and licensing requirements imposed on drug manufacturers and outsourcing facilities, rendering it ineligible to receive reimbursement for No-Fault insurance benefits.

170. Accordingly, Liberty Mutual requests a judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, declaring that Defendants have no right to receive payment for any pending bills submitted to Liberty Mutual.

THE SECOND CLAIM FOR RELIEF
Against All Defendants
(Common Law Fraud)

171. Liberty Mutual incorporates, as though fully set forth herein, each and every allegation in the paragraphs set forth above.

172. The Pharmacy Defendants and the Prescribing Defendants intentionally and knowingly made false and fraudulent statements of material fact to Liberty Mutual and concealed material facts from Liberty Mutual in the course of their submission of hundreds of fraudulent charges seeking payment for the Fraudulent Compounded Creams.

173. The false and fraudulent statements of material fact and acts of fraudulent concealment include: (i) in every claim, the representation that the billed-for services were medically necessary and properly billed in accordance with the Pharmacy Fee Schedule, when in fact the billed-for services were not medically necessary and were billed pursuant to predetermined fraudulent protocols solely to financially enrich the Defendants, based on prescriptions solicited by Woodside Chemists without regard for the topical efficacy of the compounded drug creams or the availability of a wide range of commercially available, FDA-approved medications proven to have therapeutic effects available at a fraction of the cost; (ii) in every claim, the representation that Woodside Chemists was properly licensed and, therefore, eligible to receive No-Fault Benefits pursuant to Insurance Law § 5102(a)(1) and 11 N.Y.C.R.R. § 65-3.16(a)(12), when in fact the Defendants participated in illegal, collusive agreements in which Woodside Chemists solicited and received formulaic and medically unnecessary prescriptions from licensed physicians and/or their associates for the Fraudulent Compounded Pain Creams produced by Woodside in exchange for unlawful kickbacks paid by Woodside Chemists and its alleged owner, Soni; and (iii) in every claim, the representation that Woodside Chemists was properly licensed, and therefore, eligible to receive No-Fault Benefits pursuant to Insurance Law § 5102(a)(1) and 11 N.Y.C.R.R. § 65-3.16(a)(12), when in fact Woodside Chemists engaged in illegal bulk compounding by exclusively producing and dispensing large quantities of the Fraudulent Compounded Pain Creams in set formulations, in violation of Federal and New York State regulatory and licensing requirements imposed on drug manufacturers and outsourcing facilities, rendering it ineligible to receive reimbursement for No-Fault insurance benefits.

174. The Pharmacy Defendants and Prescribing Defendants intentionally made the above-described false and fraudulent statements and concealed material facts in a calculated

effort to induce Liberty Mutual to pay charges submitted through Woodside Chemists that were not compensable under the No-Fault Laws.

175. Liberty Mutual has been injured in its business and property by reason of the above-described conduct in that it has paid approximately $20,500.00 pursuant to the fraudulent bills submitted, or caused to be submitted, by the Defendants through Woodside Chemists.

176. The Defendants' extensive fraudulent conduct demonstrates a high degree of moral turpitude and wanton dishonesty that entitles Liberty Mutual to recover punitive damages.

177. Accordingly, by virtue of the foregoing, Liberty Mutual is entitled to compensatory and punitive damages, together with interest and costs, and any other relief the Court deems just and proper.

THE THIRD CLAIM FOR RELIEF
Against the Prescribing Defendants
(Aiding and Abetting Fraud)

178. Liberty Mutual incorporates, as though fully set forth herein, each and every allegation set forth above.

179. The Prescribing Defendants knowingly aided and abetted the fraudulent scheme that was perpetrated on Liberty Mutual by the Pharmacy Defendants.

180. The acts of the Prescribing Defendants in furtherance of the fraudulent scheme include knowingly purporting to prescribe the Fraudulent Compounded Creams and permitting their names to be used in the billing, prescription records and treatment reports submitted in support of the Fraudulent Compounded Pain Creams despite their knowledge that Woodside Chemists was ineligible to bill for or to collect No-Fault Benefits in connection with the Fraudulent Services because: (i) the Defendants produced and dispensed the Fraudulent Compounded Pain Creams pursuant to predetermined fraudulent protocols solely to financially enrich themselves, based on prescriptions solicited by Woodside Chemists without regard for the

topical efficacy of the compounded drug creams or the availability of a wide range of commercially available, FDA-approved medications proven to have therapeutic effects available at a fraction of the cost; (ii) the Defendants participated in illegal, collusive agreements in which Woodside Chemists solicited and received formulaic and medically unnecessary prescriptions from licensed physicians and/or their associates for the Fraudulent Compounded Pain Creams produced by Woodside in exchange for unlawful kickbacks paid by Woodside Chemists and its alleged owner, Soni; and (iii) Woodside Chemists engaged in illegal bulk compounding by exclusively creating and dispensing large quantities of the Fraudulent Compounded Pain Creams in set formulations, in violation of Federal and New York State regulatory and licensing requirements imposed on drug manufacturers and outsourcing facilities, rendering it ineligible to receive reimbursement for No-Fault insurance benefits.

181. The conduct of the Prescribing Defendants in furtherance of the fraudulent scheme was significant and material. The conduct of the Prescribing Defendants was a necessary part of and was critical to the success of the fraudulent scheme because without their actions, there would be no opportunity for Woodside Chemists to obtain payment from Liberty Mutual and from other insurers.

182. The Prescribing Defendants aided and abetted the fraudulent scheme in a calculated effort to induce Liberty Mutual into paying charges to Woodside Chemists for medically unnecessary and illusory Fraudulent Compounded Creams that were not compensable under the No-Fault Laws, because they sought to continue profiting through the fraudulent scheme.

183. The conduct of the Prescribing Defendants caused Liberty Mutual to pay approximately $20,500.00 pursuant to the fraudulent bills that the Defendants submitted or caused to be submitted through Woodside Chemists.

184. The Defendants' extensive fraudulent conduct demonstrates a high degree of moral turpitude and wanton dishonesty that entitles Liberty Mutual to recover punitive damages.

185. Accordingly, by virtue of the foregoing, Liberty Mutual is entitled to compensatory and punitive damages, together with interest and costs, and any other relief the Court deems just and proper.

THE FOURTH CLAIM FOR RELIEF
Against All Defendants
(Unjust Enrichment)

186. Liberty Mutual incorporates, as though fully set forth herein, each and every allegation in the paragraphs set forth above.

187. As set forth above, the Pharmacy Defendants and the Prescribing Defendants have engaged in improper, unlawful, and/or unjust acts, all to the harm and detriment of Liberty Mutual.

188. When Liberty Mutual paid the bills and charges submitted by or on behalf of Woodside Chemists for No-Fault Benefits, it reasonably believed that it was legally obligated to make such payments based on the Defendants' improper, unlawful, and/or unjust acts.

189. The Defendants have been enriched at Liberty Mutual's expense by Liberty Mutual's payments, which constituted a benefit that Defendants voluntarily accepted and profited from, as a result of, among other things, the payments received and the receipt of kickback payments, notwithstanding their improper, unlawful, and unjust fraudulent billing scheme.

190. Defendants' retention of Liberty Mutual's payments violates fundamental principles of justice, equity and good conscience.

191. By reason of the above, the Defendants have been unjustly enriched in an amount to be determined at trial, but in the approximate amount of $20,500.00

JURY DEMAND

192. Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs demands a trial by jury.

WHEREFORE, Plaintiffs Liberty Mutual Insurance Company, Liberty Mutual Fire Insurance Company, Liberty Insurance Corporation, The First Liberty Insurance Corporation, LM Insurance Corporation, Liberty Mutual Mid-Atlantic Insurance Company, Liberty County Mutual Insurance Company, LM Property and Casualty Insurance Company, Safeco Company of Indiana, and American States Insurance Company demand that a judgment be entered in their favor and against the Defendants, as follows:

A. On the First Claim for Relief against the Pharmacy Defendants, a declaration pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, that Defendants, including Woodside Chemists, have no right to receive payment for any pending bills, amounting to approximately $222,400.00, submitted to Liberty Mutual;

B. On the Second Claim For Relief against the Pharmacy Defendants and the Prescribing Defendants, compensatory damages in favor of Liberty Mutual in an amount to be determined at trial but approximately $20,500.00, together with punitive damages, costs, interest and such other and further relief as this Court deems just and proper;

C. On the Third Claim For Relief against the Prescribing Defendants, compensatory damages in favor of Liberty Mutual in an amount to be determined at trial but approximately $20,500.00, together with punitive damages, costs, interest and such other and further relief as this Court deems just and proper; and

D. On the Fourth Claim for Relief against the all Defendants, a recovery in favor of Liberty Mutual in an amount to be determined at trial but approximately $20,500, together with

punitive damages, costs, interest and such other and further relief as this Court deems just and proper.

Dated: Uniondale, New York
October 27, 2017

RIVKIN RADLER LLP

By: _____
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